IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AGILENT TECHNOLOGIES, INC.,)
Plaintiff,))
V.) Civil Action No. 23-198-CJE
AXION BIOSYSTEMS, INC.,)
Defendant.)

Brian P. Egan and Travis J. Murray, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Peter J. Chassman (argued), Michael J. Forbes and Hallie H. Wimberly, REED SMITH LLP, Houston, TX; Anna M. Targowska, Allison M. Haas and Jacob M. Stone, REED SMITH LLP, Chicago, IL; Paul J. McDonnell, REED SMITH LLP, Pittsburgh, PA, Attorneys for Plaintiff Agilent Technologies, Inc.

John G. Day and Andrew C. Mayo, ASHBY & GEDDES, Wilmington, DE; Ryan K. Walsh (argued), Geoffrey K. Gavin and Laura M. Kanouse, JONES DAY, Atlanta, GA; Anna E. Raimer, JONES DAY, Houston, TX; David M. Maiorana, JONES DAY, Cleveland, OH, Attorneys for Defendant Axion Biosystems, Inc.

MEMORANDUM OPINION

Christopher Q. Burke BURKE, United States Magistrate Judge

In this patent infringement action filed by Plaintiff Agilent Technologies, Inc. ("Agilent" or "Plaintiff"), Agilent alleges infringement of United States Patent Nos. 7,192,752 (the "'752 patent"), 7,468,255 (the "'255 patent") and 8,026,080 (the "'080 patent"). (D.I. 451 at ¶ 2) Presently pending before the Court is Defendant Axion Biosystems, Inc.'s ("Axion" or "Defendant") motion for summary judgment (the "Motion") that use of Axion's CytoView-Z 96-well plates did not infringe the claims of the '752 and '255 patents (collectively, the "patents at issue"). (D.I. 348) Agilent opposes the Motion. For the reasons set forth below, the Motion is GRANTED.

I. BACKGROUND

Agilent commenced this action on February 23, 2023, asserting infringement of, *inter alia*, the patents at issue. (D.I. 1) Axion filed the instant Motion on July 10, 2025. (D.I. 348) The Motion was fully briefed as of August 29, 2025. (D.I. 425) The Court held a four-hour oral argument on the Motion on December 4, 2025. (D.I. 466 (hereinafter, "Tr.")) A jury trial in this matter is set to begin on January 26, 2026. (D.I. 188, ex. A)

The Court here writes primarily for the parties, and so any facts relevant to this Memorandum Opinion will be discussed in Section III below.

II. STANDARD OF REVIEW

The patents at issue are located on the docket in more than one place; herein, the Court will simply cite to the patents by number.

The parties have jointly consented to the Court's jurisdiction to conduct all proceedings in this case, including trial, the entry of final judgment and all post-trial proceedings. (D.I. 19)

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10 (1986). If the moving party has sufficiently demonstrated the absence of such a dispute, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Id.* at 587 (internal quotation marks, citation and emphasis omitted). If the nonmoving party fails to make a sufficient showing in this regard, then the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co.*, 475 U.S. at 586. The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Facts that could alter the outcome are "material," and a factual dispute is "genuine," only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. "If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted." *Id.* at 249-50 (internal citations omitted).

A party asserting that a fact cannot be—or, alternatively, asserting that a fact is—genuinely disputed must support the assertion either by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials;" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B).

III. DISCUSSION

The '752 patent is entitled "Real Time Electronic Cell Sensing Systems and Applications for Cell-Based Assays[,]" and it claims priority to Application No. 10/987,732, which was filed on November 12, 2004. ('752 patent at 1) The '255 patent, which is related to the '752 patent, is entitled "Method for Assaying for Natural Killer, Cytotoxic T-Lymphocyte and Neutrophil-Mediated Killing of Target Cells Using Real-Time Microelectronic Cell Sensing Technology[,]" and it claims priority to Application No. 11/197,994, which was filed on August 4, 2005. ('255 patent at 1)

Agilent asserts that Axion infringes claims 11-12, 14-18 and 20 of the '752 patent (all of which depend on independent claim 1) and claim 10 of the '255 patent (which depends on independent claim 9) (collectively, the "asserted claims"). (D.I. 361, ex. 4 at ¶ 25)³ The asserted claims of the patents at issue recite the use of, *inter alia*, multi-well cell-substrate impedance measuring devices with electrode arrays at the bottom of the wells. ('752 patent, col. 70:49-57;

Agilent also asserts claims 1-7, 9-10 and 13-14 of the '080 patent, (D.I. 361, ex. 4 at \P 25), but the '080 patent is not at issue in this Motion.

'255 patent, cols. 99:51-100:12) As relevant to this Motion, each electrode array must have "an approximately *uniform* electrode resistance distribution across [said electrode] array" (the "uniformity limitation")—with the '752 patent claims further reciting that "the electrode resistances between two locations on said array *do not differ by more than 30%*" (the "30% limitation"). ('752 patent, cols. 70:66-71:3 (emphasis added); '255 patent, col. 100:5-7 (emphasis added)) The Court has construed the uniformity limitation to have the same meaning in the patents at issue:

[E]lectrode array where the difference between resistances for two selected locations on the bottom surface of the well is not greater than 30%, regardless of the selected location, when resistance at a selected location is measured from one connection pad to the selected location and from the selected location to an opposing connection pad, excluding the gap between electrode structures of the electrode array[.]

(D.I. 159 (emphasis added); D.I. 160 (same))

Practicing the asserted claims requires the use of a machine, software, and a multi-well plate in combination. (*See, e.g.*, D.I. 361, ex. 4 at ¶¶ 27-31) Agilent alleges that various combinations of such Axion products infringe the asserted patents, including two models of Axion's multi-well plates: CytoView-Z 96-well plates ("the 96-well plates") and CytoView-Z 384-well plates. (*Id.*) This Motion concerns Agilent's infringement claims relating to the 96-well plates.

Axion's 96-well plates include some locations where the difference in resistance between them exceeds 30%. (*See, e.g.*, D.I. 401, ex. C at ¶ 161; *id.*, ex. E at ¶¶ 512-13) Accordingly, Agilent does not assert that uses of the 96-well plates literally infringe the uniformity limitation. (D.I. 361, ex. 10 at 139-40) Instead, Agilent asserts that uses of Axion's 96-well plates infringe

the uniformity limitation under the doctrine of equivalents ("DOE").⁴ (*Id.*, ex. 4 at $\P\P$ 29, 31; *id.*, ex. 5 at 13-15)

With the Motion, Axion seeks summary judgment that use of Axion's 96-well plates did not infringe the patents at issue, asserting that Agilent's DOE claims to that effect are barred by prosecution history estoppel. (D.I. 353 at 3) Below, the Court will first describe the relevant law at issue. Second, it will set out the relevant aspects of the prosecution history giving rise to the Motion. Third and finally, it will assess the parties' arguments, explaining why a grant of summary judgment is appropriate here.

A. Relevant Law Relating to DOE and Prosecution History Estoppel

"Even when an accused product does not meet each and every claim element literally, it may nevertheless be found to infringe the claim if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Intendis GmbH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355, 1360 (Fed. Cir. 2016) (certain internal quotation marks and citations omitted). The DOE is applied to individual elements of the claim,

The language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its

A patentee can assert that an accused infringer directly infringes a patent either by literal infringement or under the DOE. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005); *Med-El Elektromedizinische Gerate Ges.M.B.H. v. Advanced Bionics, LLC*, Case No. 1:18-cv-01530-JDW, 2024 WL 4371292, at *6 (D. Del. Oct. 2, 2024). "Literal infringement exists if each of the limitations of the asserted claim(s) read on, that is, are found in, the accused device." *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995); *Med-El Elektromedizinische Gerate Ges.M.B.H. v. Advanced Bionics, LLC*, 2024 WL 4371292, at *6. The DOE will be discussed in more detail below.

The Supreme Court of the United States has explained the philosophy behind the DOE as follows:

not to the invention as a whole. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). Infringement under the DOE is a question of fact. *Intendis GmbH*, 822 F.3d at 1360.

However, prosecution history estoppel may prevent a patentee from using the DOE to recapture subject matter surrendered from the literal scope of a claim during prosecution.

Trading Techs. Int'l, Inc. v. Open E Cry, LLC, 728 F.3d 1309, 1322 (Fed. Cir. 2013).

Prosecution history estoppel is a "rule of patent construction[,]" Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. [hereafter, "Festo VIII"], 535 U.S. 722, 733 (2002), that is implicated when "an applicant during prosecution either makes an argument evincing a 'clear and unmistakable surrender' of subject matter ['argument-based prosecution history estoppel'] . . . or narrows a claim 'to avoid the prior art, or otherwise to address a specific concern . . . that arguably would have rendered the claimed subject matter unpatentable' ['amendment-based prosecution history estoppel'][,]" Spectrum Pharms., Inc. v. Sandoz Inc., 802 F.3d 1326, 1337 (Fed. Cir. 2015) (citations omitted). If either (or both) of these circumstances occurs, the applicant is then estopped from later invoking the DOE to recapture the surrendered subject

novelty. If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying. For this reason, the clearest rule of patent interpretation, literalism, may conserve judicial resources but is not necessarily the most efficient rule. The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731-32 (2002).

The specifics of amendment-based and argument-based prosecution history estoppel will be discussed in more detail below.

matter. *Id.* Whether prosecution history estoppel applies, and therefore whether a patentee may assert the DOE for a particular claim limitation, is a question of law for the Court. *Id.*; *Integra LifeScis. Corp. v. HyperBranch Med. Tech., Inc.*, Civil Action No. 15-819-LPS-CJB, 2018 WL 1037044, at *12 (D. Del. Feb. 20, 2018).

B. Relevant Facts Relating to the Prosecution History

During prosecution of the '752 patent, the sole original independent claim presented for examination was application claim 51 ("claim 51"). (D.I. 361, ex. 12 at AGILE0000588-91)

Claim 51 did not include the uniformity limitation—or, for that matter, any limitations at all regarding the electrode array's resistance or resistance distribution. (*Id.*)⁸ Nor did any of the

A system for monitoring cell-substrate impedance, comprising:

While rebuttal of a presumption of prosecution history estoppel (discussed further below) may involve underlying facts, the resolution of any such factual issues is itself also a matter for the Court. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368 n.3 (Fed. Cir. 2003) (en banc); *Sun Pharm. Indus. Ltd. v. Saptalis Pharms., LLC*, Civil Action No. 18-648-WCB, 2019 WL 13153693, at *17 (D. Del. Aug. 26, 2019).

⁸ At that time, Claim 51 recited:

a) one or more multiple well cell-substrate impedance monitoring devices, wherein at least two of the multiple wells of said device comprise an electrode array at the bottom of the well, wherein said electrode array is individually addressed, further wherein said device can be used to measure differences in impedance values that relate to cell behavior;

b) an impedance analyzer;

c) a device station comprising electronic circuitry that can engage said device and selectively connect said two or more electrode arrays of said device to said impedance analyzer; and

d) a software program that can [] control [said] device station and record and analyze data obtained from said impedance analyzer.

other then-pending dependent claims. (*Id.*) On June 15, 2005, the United States Patent and Trademark Office ("PTO") provisionally rejected the pending claims for obviousness-type double patenting ("OTDP"), asserting that the claims were unpatentable over a co-pending application of the patentee (the "initial Office Action"). (*Id.* at AGILE0000392-96)⁹ The PTO noted that the applicants could file a terminal disclaimer to overcome the rejection. (*Id.* at AGILE0000394)¹⁰

In September 2005, the applicants responded to the initial Office Action. (*Id.* at AGILE0000354-60) The applicants did not file a terminal disclaimer; instead, they amended claim 51 to add the uniformity limitation—i.e., claim 51 now specified "wherein said electrode array has an approximately uniform electrode resistance distribution across said electrode array" (the "first amendment"). (*Id.* at AGILE0000355) The applicants explained that they were making this amendment "to expedite allowance of the present application" and noted that the

⁽D.I. 361, ex. 12 at AGILE000588) Claim 51 was then identical to what is now claim 1 of the '752 patent, except that claim 1 of the '752 patent also has a "wherein" clause after limitation (d) that includes the uniformity limitation and the 30% limitation. (*See* '752 patent, cols. 70:49-71:3)

OTDP "is a judicially-created doctrine designed to prevent claims in separate applications or patents that do not recite the same invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (internal quotation marks and citation omitted). Under the OTDP doctrine, a patentee is prohibited "from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Lab'ys, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

A terminal disclaimer allows an applicant to avoid an OTDP rejection by "disclaiming that portion of the second patent which would extend beyond the expiration of the first[.]" *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed. Cir. 1992); *see also* 37 C.F.R. § 1.321(b)-(c).

claims of the co-pending application did not recite the uniformity limitation. (*Id.* at AGILE0000359-60) As will be discussed in detail below, Axion asserts that this first amendment gives rise to amendment-based prosecution history estoppel.

The PTO responded with an Office Action (the "second Office Action") in December 2005, in which it, *inter alia*, modified the OTDP rejection to add a prior art reference called "Pancrazio" and also rejected the pending claims as anticipated by Pancrazio. (*Id.* at AGILE0000335-40) The PTO asserted that while the co-pending application was silent with regard to, *inter alia*, uniform electrode resistance, Pancrazio disclosed a device for monitoring cell impedance using an array with electrodes having "substantially uniform electrical resistance." (*Id.* at AGILE0000337)

In April 2006, the applicants responded to the second Office Action by arguing against the OTDP rejection and the anticipation rejection in view of Pancrazio. (*Id.* at AGILE0000312-18) With respect to the OTDP rejection, the applicants explained that Pancrazio "does not disclose an array with uniform electrode resistance" while the present application discussed "[u]niform electrode resistance . . . throughout the specification[.]" (*Id.* at AGILE0000312-13) The applicants noted that "[p]roviding an array with approximate uniform resistance is one important aspect of the present application as filed." (*Id.* at AGILE0000313) As for Pancrazio, the applicants explained that:

Referring to the above provided discussion regarding uniform electrode resistance, Pancrazio et al. do not disclose an array with approximate uniform electrode resistance. More specifically, Pancrazio et al. demonstrate an electrode array including electrodes and interconnecting traces having a variety of lengths and spaces. The lengths of the electrodes, the interconnecting traces and the spaces between them contribute to the electrode resistance across the array. Therefore an array with a variety of

lengths and spaces would yield a variety of resistances across the array and not be approximately uniform.

(*Id.* at AGILE0000314)

With respect to anticipation, the applicants reiterated that Pancrazio did not disclose "an electrode array having approximate uniform resistance across the electrode array" and incorporated by reference the arguments that they had made in response to the OTDP rejection. (Id. at AGILE0000316; see also id. at AGILE0000315, AGILE0000318) They again emphasized that Pancrazio "demonstrates an electrode array having electrodes and interconnecting traces having a variety of lengths and spaces" and that these lengths and spaces "affect the electrode resistance across the array" such that "an array with a variety of lengths and spaces would not yield an approximate uniform electrode resistance without further modification." (Id. at AGILE0000317) Turning to the applicants' claims, the applicants argued that:

The present invention addresses the problem of variations in electrode resistance occurring across an array for cell-substrate impedance measurement and has provided a solution to create an approximate uniform resistance across the array. Referring to page 28, lines 5-9 of the present application,

"[A uniform electrode resistance] can be achieved, for example by having electrode structures and electrode buses of particular spacing and dimensions (lengths, widths, thicknesses and geometrical shapes) such that the resistance at any single location of the array is approximately equal to the resistance at any single other location on the array."

(*Id.*) As will be discussed further below, these arguments relating to Pancrazio form the basis of Axion's argument-based prosecution history estoppel contention.

In July 2006, the PTO rejected the pending claims as indefinite pursuant to 35 U.S.C. § 112; there, the PTO asserted that the uniformity limitation is a relative term and without it being clearly defined, the claims were indistinguishable from the prior art (the "third Office Action"). (*Id.* at AGILE0000300-03) In response to the third Office Action, the applicants amended claim 51 to add the 30% limitation and explained that this amendment was for "allowance and for clarity[.]" (*Id.* at AGILE0000292, AGILE0000298) Claim 51 was then allowed and renumbered as claim 1 of the '752 patent. (*Id.* at AGILE0000283-84)

The claims of the '255 patent were examined in 2007 and 2008. (*Id.*, ex. 16) Claim 10 of the '255 patent issued with the uniformity limitation but without the 30% limitation. ('255 patent, cols. 99:51-100:12)

C. The Parties' Arguments and the Court's Analysis

Axion makes three arguments as to why prosecution history estoppel applies. Two of those arguments involve amendment-based prosecution history estoppel and one involves argument-based prosecution history estoppel. Below, the Court will explain why it agrees with Axion regarding two of these arguments (one of Axion's amendment-based estoppel arguments and its argument-based estoppel contention). The result of this analysis is that Agilent is precluded from relying on the DOE with respect to the uniformity limitation. ¹¹

1. Axion's Amendment-based Prosecution History Estoppel Argument Axion first argues that Agilent is precluded from relying on the DOE to assert that uses of

Because the Court agrees with Axion that prosecution history estoppel applies with respect to these two arguments, it need not and does not address Axion's third, independent argument as to why prosecution history estoppel bars application of the DOE here. (*See* D.I. 425 at 4-5 & n.8)

Axion's 96-well plates infringe the uniformity limitation of the patents at issue in view of the first amendment described above. ¹² For the reasons set out below, the Court agrees.

The analysis for amendment-based prosecution history estoppel is a bit complicated, in that it possibly implicates two different presumptions and involves up to four different questions that must be answered. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* [hereafter, "Festo IX"], 344 F.3d 1359, 1366-67 (Fed. Cir. 2003) (en banc); see also, e.g., UCB, Inc. v. Yeda Rsch. & Dev. Co., 117 F. Supp. 3d 755, 775 (E.D. Va. 2015), aff'd, 837 F.3d 1256 (Fed. Cir. 2016); Annotated Patent Digest (Matthews), § 14:11.

This four-question process breaks down as follows:

- The first question is whether an amendment filed with the PTO has narrowed the literal scope of a claim. If the amendment was not narrowing, then the analysis ends and prosecution history estoppel does not apply. But if the accused infringer establishes that the amendment was a narrowing one, the analysis proceeds to the second question. *Festo IX*, 344 F.3d at 1366; *UCB*, *Inc.*, 117 F. Supp. 3d at 775.
- The second question is whether the reason for that narrowing amendment was a substantial one relating to patentability. If the patentee successfully establishes that the amendment was not for a reason of patentability, then the inquiry likely ends. If, however, the court determines that the narrowing amendment was made for a substantial reason relating to patentability, we move to the third question. *Festo IX*, 344 F.3d at 1366-67; *UCB, Inc.*, 117 F. Supp.

Although the first amendment took place during prosecution of the '752 patent, there is no dispute that the Court's analysis here regarding the relevant prosecution history for the '752 patent is applicable to the '255 patent for purposes of these issues—and that therefore whether prosecution history estoppel applies with respect to the '255 patent rises and falls with the Court's conclusion as to the '752 patent. (D.I. 353 at 11-12; D.I. 392 at 21; D.I. 425 at 10; see also Tr. at 84) While the Court therefore focuses its discussion herein on the '752 patent, the same conclusion applies to the '255 patent.

3d at 775.13

- The third question (which, admittedly, tends to collapse a bit into the fourth question) addresses the scope of the subject matter surrendered by the narrowing amendment, and whether the equivalent at issue falls within that scope. Festo IX, 344 F.3d at 1367. Here, a presumption attaches that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation. Id.; UCB, Inc., 117 F. Supp. 3d at 775. If the Court determines that the equivalent falls within the scope of the subject matter that was surrendered, then we move to the fourth question.
- Finally, the fourth question asks whether the patentee has rebutted the presumption of total surrender by establishing one or more of three exceptions to estoppel: "[1] the equivalent [was] unforeseeable at the time of the application; [2] the rationale underlying the amendment [bore] no more than a tangential relation to the equivalent in question; or [3] there [was] some other reason suggesting that the patentee could not reasonably be expected to have described the [equivalent]." Festo VIII, 535 U.S. at 740-41; see also Integra LifeScis. Corp., 2018 WL 1037044, at *12; UCB, Inc., 117 F. Supp. 3d at 775. If the patentee fails to establish one of these exceptions, then prosecution history estoppel bars the patentee from relying on the DOE for the accused element. Festo IX, 344 F.3d at 1367. But if the patentee successfully rebuts the presumption of total surrender, then prosecution history estoppel does not apply, and the DOE analysis is reached on the merits. Id.

The Court will now analyze the parties' arguments regarding these four questions.

a. Was there a narrowing amendment?

If the prosecution history record does not reveal a reason for the narrowing amendment, a presumption applies that the patentee had a substantial reason relating to patentability for the amendment that the patentee must overcome. *Festo IX*, 344 F.3d at 1366-67.

On the first question, there is now no dispute that the first amendment narrowed the literal scope of the claims.¹⁴ Where before claim 51 did not require the electrode array to have approximately uniform electrode resistance distribution across the array, the first amendment resulted in a requirement that the claimed electrode array now must have such uniform resistance distribution. (D.I. 353 at 6; D.I. 425 at 2)

b. Was the reason for the narrowing amendment a substantial one relating to patentability?

There is a fight between the parties with regard to the second question—i.e., whether the reason for the first amendment "was a substantial one relating to patentability." *Festo IX*, 344 F.3d at 1366. Agilent argues that the answer to this question is no. It asserts this is so because only amendments made for any reason related to the *statutory requirements* for a patent count as being made for a "substantial [reason] relating to patentability"—such that the presumption does not apply here as a matter of law, because the first amendment was made following a *non-statutory* OTPD rejection. (D.I. 392 at 8; Tr. at 80; Agilent's Summary Judgment Hearing Presentation, Slide 22) Axion, for its part, retorts that the first amendment was made for

Agilent *did* seem to dispute this issue in its briefing. There it asserted that prosecution history estoppel does not apply because, *inter alia*, the applicants *added* the uniformity limitation and thus did not narrow a claim limitation implicating the concept of uniformity *that was already present in the claims*. (D.I. 392 at 8-9) But by the time of oral argument, Agilent wisely conceded that the claim scope here was indeed narrowed with the addition of the uniformity limitation. (Tr. at 106, 112-13); *see also Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1140 (Fed. Cir. 2004) ("[A] narrowing amendment may occur when either (1) a preexisting claim limitation is narrowed by amendment or (2) a new claim limitation is added by amendment."). In other words, if the prior version of claim 51 didn't have any limitation in it at all regarding the concept of uniformity (as here), and then the uniformity limitation was added to the claim (as here), then *of course* that addition narrowed the claim—in that it now made clear for the first time that the only type of system that infringes the claim is one that employs the requisite electrode array having an approximately uniform electrode resistance distribution across the entire array.

substantial reasons relating to patentability—and that as a result, the inquiry must then proceed to the third question. (D.I. 425 at 3)

For the following three reasons, the Court agrees with Axion. In doing so, it concludes that if a narrowing claim amendment is made in order to overcome a non-statutory OTPD rejection, then the reason for that limitation qualifies as being "a substantial one relating to patentability."

First, the caselaw does not support Agilent's position that prosecution history estoppel does not apply as a matter of law if a narrowing amendment is made in response to a nonstatutory rejection. Agilent's briefing on this issue was sparse. (D.I. 392 at 8) There, Agilent simply: (1) quoted a decision of the United States Court of Appeals for the Federal Circuit in Bose Corp. v. JBL, Inc., 274 F.3d 1354 (Fed. Cir. 2001), wherein the Federal Circuit stated that "[a] narrowing amendment made for any reason related to the statutory requirements for a patent will give rise to [prosecution history estoppel] with respect to the amended claim element[;]" and (2) then asserted that since the amendment here was made following a *non-statutory* rejection, prosecution history estoppel does not apply. (*Id.* (emphasis in original) (quoting *Bose Corp.*, 274 F.3d at 1359)). Now, of course Agilent is correct that in *Bose*, as noted above, the Federal Circuit did use the term "statutory requirements" when making reference to this part of the estoppel inquiry. But Bose does not help Agilent here, because that opinion simply wasn't speaking to the issue of whether a narrowing amendment related to a "non-statutory" requirement like OTDP could also give rise to prosecution history estoppel. See Bose, 274 F.3d at 1359-60 (concluding that the patentee's amendment was not a narrowing amendment, and thus declining to go on and "examine the reason why the applicant amended the claim").

During oral argument, when asked for the best case that supported its position, Agilent pointed to *Festo VIII*. (Tr. at 92, 97) But that case also does not win the day for Agilent here. It is true that on the one hand, in *Festo VIII*, the Supreme Court of the United States acknowledged its agreement with the Federal Circuit that "a narrowing amendment made to satisfy any *requirement of the Patent Act* may give rise to an estoppel[,]" explaining that:

As that court explained, a number of *statutory requirements* must be satisfied before a patent can issue. The claimed subject matter must be useful, novel, and not obvious. 35 U.S.C. §§ 101-103.... In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention. § 112.... These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public.

Festo VIII, 535 U.S. at 736 (emphasis added). But on the other hand, like in Bose, Festo VIII does not speak to the specific question of whether a rejection based on a non-statutory requirement can also give rise to prosecution history estoppel. And so the case certainly does not stand for the proposition that it cannot.

In fact, if anything, *Festo VIII* suggests that Axion has the correct view on this issue. (Tr. at 140-41) The petitioner in that case had argued that prosecution history estoppel should arise only in circumstances where an amendment was made to avoid prior art—and not when a narrowing amendment was made to comply with Section 112 of the Patent Act. *Festo VIII*, 535 U.S. at 729, 735. The Supreme Court disagreed with the petitioner, finding that application of prosecution history estoppel was broader than just in circumstances where an amendment was made to avoid prior art. In that vein, the *Festo VIII* Court explained that in its prior cases on the doctrine, the Supreme Court had established that "estoppel applies to amendments made for a 'substantial reason related to patentability'" but noted that it had *not* "purport[ed] to define that

term or to catalog every reason that might raise an estoppel. Indeed, [the Court had] stated that even if the amendment's purpose were *unrelated* to patentability, [it] might consider whether [this] was the kind of reason that nonetheless might require resort to the estoppel doctrine." *Id.* at 735 (emphasis added). The *Festo VIII* Court continued that even though prosecution history estoppel had been previously discussed most frequently in the context of amendments made to avoid prior art,

[i]t does not follow . . . that amendments made for other purposes will not give rise to estoppel. Prosecution history may rebut the inference that a thing not described was indescribable. *That rationale does not cease simply because the narrowing amendment, submitted to secure a patent, was for some purpose other than avoiding prior art.*

Id. at 735-36 (emphasis added). And the Supreme Court summed up things by stating that "[e]stoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope." Id. at 736. The Festo VIII Court's rationale here signals that if a narrowing amendment is made to "secure the patent[,]" full stop, then prosecution history estoppel can arise—regardless of whether the patentability-related rejection that the amendment is intended to overcome is based on a statute (e.g., Sections 102, 103 or 112 of the Patent Act) or involves a judicially-created, non-statutory barrier to patentability (i.e., OTDP). 15

For what it is worth—and despite the language used in cases like *Festo VIII* and *Bose*—there are a host of Federal Circuit opinions analyzing prosecution history estoppel that do not make reference to the "statutory" language that Agilent clings to here. *See, e.g., Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1364 (Fed. Cir. 2020) ("Prosecution history estoppel arises when a patent applicant narrows the scope of his claims during prosecution for a reason 'substantial[ly] . . . relating to patentability."") (citation omitted); *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010) (similar); *Honeywell Int'l Inc.*, 370 F.3d at 1139 ("Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent[']s scope.").

While the parties could not point the Court to any cases holding that prosecution history estoppel does *not* attach as a matter of law where a narrowing amendment was made to overcome a non-statutory rejection, (*see* Tr. at 93), at least one court has determined that the doctrine *does* attach in such a case (thus flatly rejecting Agilent's position to the contrary). In *Dahl v. Swift Distribs., Inc.*, 757 F. Supp. 2d 976 (C.D. Cal. 2010), the plaintiff had argued that prosecution history estoppel only arises when a narrowing amendment is made in response to a "statutory rejection" (i.e., one based on 35 U.S.C. §§ 102, 103, or 112). *Dahl*, 757 F. Supp. 2d at 985 (*cited in* D.I. 425 at 2). The *Dahl* Court found this argument to be unsupported by any legal authority. *Id.* In the end, then, the relevant caselaw supports Axion's position here.

Second, it really doesn't make much sense to the Court that overcoming a OTDP rejection would not qualify as a "substantial [reason] relating to patentability" in this context, simply because OTDP is a *judicially-created* barrier to patentability and not a *statutory* barrier. ¹⁶ Tellingly, when the Court asked Agilent's counsel during oral argument why this difference (statutory vs. non-statutory) should make a difference here, Agilent's counsel did not have a good answer. Instead, counsel simply reiterated that there are certain judicial opinions (discussed above) that include the word "statutory" when setting out the contours of this portion of question two. (Tr. at 96-97)

The Court notes that neither party could think of another example of a non-statutory rejection relating to patentability, other than OTDP. (Tr. at 41-42, 94) So it does not seem that the Court's holding here would widely extend the reach of prosecution history estoppel. Even as regarding an OTDP rejection, Axion asserts that most applicants opt to file a terminal disclaimer instead of submitting an amended claim (which is why we don't see this particular issue come up much in the caselaw). (*Id.* at 27, 43)

In the Court's view, it is notable that the Federal Circuit has found that OTDP *is* a challenge to "patentability" in a different context (i.e., one that involved a challenge to the denial of patent term adjustments). *SawStop Holding LLC v. Vidal*, 48 F.4th 1355, 1364 (Fed. Cir. 2022) (noting that the claim at issue was "unpatentable" because of, *inter alia*, an OTDP rejection, and rejecting the patentee's argument that the "rejection did not affect 'patentability' because it was non-statutory (because it was an [OTDP] rejection) and provisional (because the obviousness-rendering reference was an application rather than a patent)[,]" noting that such a rejection "had legal effect" and was not "illusory"). If OTDP is a challenge to "patentability," then narrowing a patent claim to overcome that type of challenge has to be an act done for a reason "relating to patentability."

Indeed, the scenario here matches up neatly with the *Festo VIII* Court's broader discussion of the application of prosecution history estoppel. The Court there explained that "[a] rejection indicates that the patent examiner does not believe the original claim could be patented[,]" and that prosecution history estoppel arises when a responsive narrowing amendment "is made to secure the patent[.]" 535 U.S. at 734, 736. Here, as discussed above, that's exactly what happened. That is, the Examiner issued a "rejection" of claim 51 on the ground that the claim "could [not] be patented" pursuant to OTDP in view of certain claims in a co-pending application. (D.I. 361, ex. 12 at AGILE0000394) And then the applicants, noting that the Examiner had rejected the claims "as allegedly being unpatentable[,]" chose to make a narrowing amendment to the claim in response, in order to secure the patent. (*Id.* at AGILE0000359-60; *see also* Tr. at 27, 46; Axion's Summary Judgment Presentation Slides at

Slide 28 ("An [OTDP] rejection prevents a patent."))¹⁷ The Court sees no good reason why estoppel should not apply in such a circumstance—one where a narrowing amendment was clearly made for a "substantial [reason] relating to patentability."

Third, from a policy perspective, it is understandable why prosecution history estoppel would apply to narrowing amendments made to overcome an OTDP rejection (even though such a rejection is non-statutory). After all, the prosecution history estoppel doctrine "is founded on the public notice function of patents[,]" *Pac. Coast Marine Windshields Ltd. v. Malibu Boats*, *LLC*, 739 F.3d 694, 700 (Fed. Cir. 2014), and it prevents the patentee from "recaptur[ing] in an infringement action the very subject matter surrendered as a condition of receiving the patent[,]" *Festo VIII*, 535 U.S. at 734. Whether a narrowing amendment is made to overcome a rejection based on Section 102 or 103 or 112, or whether it is made to overcome a rejection based on OTDP, the patentee is, in all of these circumstances, conveying to the public what the patent does and does not cover. (*See* Tr. at 5, 28-29)

For all of these reasons, the Court finds that the reason for the first amendment was a substantial one relating to patentability.

It bears emphasis here that, as noted above, the applicants did not have to narrow claim 51 in response to the rejection. Instead, they could have filed a terminal disclaimer and not changed the claim scope, in exchange for agreeing to an earlier expiration date for the '752 patent. (D.I. 361, ex. 12 at AGILE0000394; *see also* D.I. 425 at 4 n.7) But the applicants didn't want to do that. They chose instead to narrow the claim scope—i.e., to change a claim that did not include any limitations regarding the electrode array's resistance into a claim that now required an approximately uniform electrode resistance distribution. And they did so in order to secure the '752 patent without a restriction on the expiration date of that patent. (D.I. 361, ex. 12 at AGILE0000359-60 (applicants telling the Examiner that they amended claim 51 to include the uniformity limitation, which was not recited in the claims of the co-pending application at issue in the Examiner's OTDP rejection)); *see Festo VIII*, 535 U.S. at 734 (noting that a patentee's decision to "submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim"). That decision had consequences.

c. Does the equivalent at issue fall within the scope of the subject matter surrendered by the narrowing amendment?

The Court now turns to the third question, which assesses whether the alleged equivalent falls within the scope of the subject matter surrendered by the narrowing amendment.

What was the scope of the subject matter surrendered by the amendment at issue? As discussed above, claim 51 originally had no restriction on the resistance distributions of the claimed electrode arrays. But the applicants narrowed that claim to require that the electrode arrays now must have an approximately uniform electrode resistance distribution across the arrays. So the applicants surrendered arrays that do *not* have approximately uniform electrode resistance distribution.

Does Axion's equivalent fall within that surrendered scope? There can be no real dispute that it does. The equivalent undisputedly includes multiple locations where the resistance at one location differs by more than 30% from other locations on the array; thus, it does not have an approximately uniform electrode resistance distribution across the electrode array. (*See, e.g.*, D.I. 401, ex. C at ¶ 161; *id.*, ex. E at ¶¶ 512-13; Tr. at 30-31, 89)

d. Has the patentee rebutted the presumption of total surrender by establishing one of three exceptions to estoppel?

There is another dispute between the parties, which relates to the fourth question. As noted above, this question assesses whether Agilent has rebutted the presumption that prosecution history estoppel applies. Here, Agilent asserts that only one exception is applicable. That is, it argues that prosecution history estoppel does not apply because the first amendment bears no more than a "tangential relation to the equivalent in question" (again, the equivalent being an electrode array as to which there are multiple instances wherein the resistance at one

location on the array differs by more than 30% from that at another location on the array). (D.I. 392 at 10-11 (citation omitted))

The Federal Circuit requires a "strong showing" to satisfy the "very narrow" tangential relation exception. *Energy Transp. Grp., Inc. v. William Demant Holding A/S*, 697 F.3d 1342, 1359 (Fed. Cir. 2012) (citation omitted); *see also* (Tr. at 111). The inquiry focuses on "the patentee's objectively apparent reason for the narrowing amendment." *Festo IX*, 344 F.3d at 1369. To rebut the presumption of prosecution history estoppel with tangentiality, a patentee must demonstrate that "the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315 (Fed. Cir. 2008) (citation omitted). The reason for the narrowing amendment should be discernible from the prosecution history; if no reason is revealed therein, the presumption is not rebutted. *Id.* at 1315-16.

In its briefing, Agilent seems to argue that because claim 51 didn't have a preexisting uniformity limitation when the first amendment was submitted, then the first amendment bears no relation to Axion's equivalent "where the equivalence concerns the uniformity limitation." (D.I. 392 at 11) Agilent's argument in this regard is not very clear, and certainly is not persuasive. The reason for the first amendment was obvious. There, the applicants added the requirement for electrode arrays with resistances at every location that are approximately uniform to a claim that previously had no limitation relating to the resistances of such arrays—and it did so in order to overcome the Examiner's OTDP rejection (since the claims of the copending application did not have such a uniformity requirement). (D.I. 361, ex. 12 at AGILE0000359-60; *see also* Tr. at 114, 116 (Agilent's counsel acknowledging that the first

amendment was all about uniformity of the resistance distributions across the electrode arrays)) Thus, the first amendment is not merely tangential to—and instead directly implicates—an alleged equivalent having electrode arrays with resistances at multiple locations that are not approximately uniform. See, e.g., Duramed Pharms., Inc. v. Paddock Lab'ys, Inc., 715 F. Supp. 2d 552, 564-65 (S.D.N.Y. 2010) (explaining that "[t]he essential question here is whether the reason behind the narrowing amendment implicates the alleged equivalent[,]" and finding that the patentee did not meet its burden of demonstrating the tangentiality exception, where "the narrowing amendment related only to the type of moisture barrier coating used, and the alleged equivalent is a different type of moisture barrier coating" such that the patentee's narrowing amendment was not tangential to the alleged equivalent), aff'd, 644 F.3d 1376 (Fed. Cir. 2011); Sears Petroleum & Transport Corp. v. Archer Daniels Midland Co., 558 F. Supp. 2d 273, 282 (N.D.N.Y. 2008) ("[I]t cannot be said that the narrowing bore little relationship to the equivalent in question. The very purpose of the amendment was to define the weight ranges of cellulose derivatives and carbohydrates for use as thickeners in order to eliminate the examiner's indefiniteness concerns. Since the CALIBER equivalents now urged by Sears as equivalents include carbohydrates outside of the specified range, the rationale for amendment bore significantly more than a tangential relationship to the accused equivalent.").

Having now proceeded through all four questions of the prosecution history estoppel record, the Court concludes that prosecution history estoppel applies to the first amendment.

This in turn bars Agilent from relying on the DOE to assert that the accused equivalent satisfies the uniformity limitation. Nevertheless, the Court will now explain why it also agrees that

Axion's argument-based prosecution history estoppel argument amounts to a second, independent reason to grant the Motion.

2. Axion's Argument-based Prosecution History Estoppel Argument

Axion also argues that Agilent is precluded from relying on the DOE to assert that uses of Axion's 96-well plates infringe the uniformity limitation, in view of the arguments applicants made when distinguishing their claims from the Pancrazio reference. (D.I. 353 at 8; D.I. 425 at 5-6) Argument-based estoppel prevents a patentee from asserting the DOE against an accused product encompassed by subject matter surrendered by the applicant's arguments to the PTO. *Amgen Inc. v. Coherus BioScis., Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019); *San Rocco Therapeutics, LLC v. Bluebird Bio, Inc.*, Civil Action No. 21-1478-RGA, 2025 WL 1425341, at *6 (D. Del. May 16, 2025). "To invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter." *Amgen Inc.*, 931 F.3d at 1159 (internal quotation marks and citations omitted). "[C]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may [] create an estoppel . . . [t]he relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.* at 1159-60.

Axion asserts that argument-based prosecution history estoppel applies here because in addition to asserting multiple times that Pancrazio does not disclose an array with approximate uniform electrode resistance, the applicants emphasized that "[t]he present invention addresses the problems of variations in electrode resistance occurring across an array . . . and has provided a solution to create an *approximate uniform resistance across the array*" by "having [for example] electrode structures and electrode buses of particular spacing and dimensions *such that*

the resistance at any single location of the array is approximately equal to the resistance at any single other location on the array." (D.I. 353 at 6-7 (quoting D.I. 361, ex. 12 at AGILE0000312, -314, -317) (emphasis added)) The Court agrees that the meaning of these comments is clear and unmistakable. With them, the applicants unequivocally surrendered the subject matter of electrode arrays that did not have approximate uniform electrode resistance across the arrays (such that the resistance at any single location of the array was not approximately equal to the resistance at any other location on the array). (See id. at 8; D.I. 425 at 5-6); see, e.g., San Rocco Therapeutics, LLC, 2025 WL 1425341, at *6-7 (finding that argument-based prosecution history estoppel applied, where the applicant emphasized repeatedly during prosecution that the claimed nucleotide fragment is 3.2 kb, thus clearly and unmistakably surrendering subject matter, and where the accused product was 2.7 kb (i.e., falling within the scope of that surrendered subject matter)); Pactiv, LLC v. Multisorb Techs., Inc., 63 F. Supp. 3d 832, 838 (N.D. Ill. 2014) (concluding that because the applicants distinguished the invention from hydrogen annealed iron that had not been electrolytically reduced, prosecution history estoppel prevented them from accusing defendant's iron product which was not electrolytically reduced and was thus "precisely the type of iron that [the applicant] sought to distance its invention from during the prosecution of the" asserted patent), aff'd, 621 F. App'x 665 (Fed. Cir. 2015).

Agilent's counter arguments were not persuasive. In its briefing, Agilent's position against the applicability of argument-based estoppel went like so:

• The applicants asserted that Pancrazio was distinguishable from the uniformity limitation in the applicants' invention by noting that: (1) Pancrazio's array had electrodes and interconnecting traces having a "variety of lengths and spaces[;]" and (2) because the lengths of the electrodes and interconnecting traces and the spaces between them all affect the electrode resistance, such an

array would not yield uniform resistance "without further modification." (D.I. 392 at 19 (quoting D.I. 361, ex. 12 at AGILE0000317) (emphasis omitted); *see also id.* ("Applicants . . . argued that Pancrazio did not disclose enough detail to determine whether or not the uniformity limitation was met."))

- Axion's argument that its equivalent is captured by the subject matter surrendered by the applicants because it has electrodes with a variety of lengths is erroneous, because the applicants did not unilaterally surrender all arrays with electrodes of varying lengths and spaces (let alone just varying lengths)—rather, such an electrode could still fall within the scope of the claims *if* it was designed for uniformity via "further modification." (*Id*.)
- Even if the applicants *did* surrender arrays with electrodes of a variety of "lengths and spaces" when distinguishing Pancrazio, Axion's equivalent still does not fall within the territory of that surrender because it includes a variety of lengths, but not a variety of spaces. (*Id.* at 19-20)

But Agilent's emphasis on the "lengths and spaces" of the electrode array is a red herring. It is true that in the quoted material above, the patentee did discuss Pancrazio's array, and how that array's electrodes and interconnecting traces had a variety of lengths and spaces. But the key point for our purposes is that as part of that discussion, the take-away point delivered by the patentee was that *its invention has an "approximate uniform electrode resistance"* and that *Pancrazio did not.* (*See* Tr. at 129-30 (Axion's counsel acknowledging that during prosecution, the applicants were clearly "saying [that] our claims require uniformity"); *see also id.* at 26, 62, 64-68) So the bottom line is that the patentee clearly there disclaimed arrays that do *not* have an approximate uniform electrode resistance—like Axion's 96-well plates. (D.I. 425 at 6)

In sum, the Court agrees with Axion that in light of the applicants' arguments distinguishing their claims from Pancrazio, prosecution history estoppel bars Agilent from now recapturing in this case the equivalent that it surrendered as a condition of receiving the patents

at issue—i.e., an electrode array with resistance at locations on the array that are not approximately equal to the resistance at other locations on the array.

IV. CONCLUSION

For the foregoing reasons, the Court orders that the Motion is GRANTED. An appropriate Order will issue.